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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,768	05/27/2005	Naoaki Taoka	Q88078	2449

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EXAMINER	
SAUCIER, SANDRA E	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
09/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,768	TAOKA ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-31* is/are pending in the application.

4a) Of the above claim(s) *27-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-16,23 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/27/05*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 7-31 are pending. Claims 7-26 are considered on the merits. Claims 27-31 are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Applicant's election with traverse of Group I in the reply filed on 7/25/07 is acknowledged. The traversal is on the ground that the compound of Group II is obtainable by the process of Group I, and the compound of Group II is a suitable starting material for the process of Group I. This is not found persuasive because the compound of Group II is not the product of the process of Group I because Group I gives a range of products. An anticipatory reference over Claim 1 does not necessarily anticipate the product of Claim 27. Further, under unity of invention rules, multiple products are not allowed in a single category, see page 3 of the restriction of 6/25/07.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The disclosure is objected to because of the following informalities: Reference to PCT/JP/03/15644 should appear in the first paragraph. Appropriate correction is required.

Priority

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in JAPAN 2002-355305 on 12/6/02. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application (PCT/JP03/15644) was filed more than twelve months thereafter.

Claim Rejections - 35 USC § 112

DEPOSIT

Claims 10, 12, 14, 23, 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention.

At least some of the claims require one of ordinary skill in the art to have access to a specific microorganism. Because the microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not clear from the specification or record that the microorganism is readily available to the public.

The objection and accompanying rejection may be overcome by establishing that each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. See 37 CFR 1.801-1.809. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37 CFR 1.808.

If the deposit is not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria, assurance must be provided to the effect that:
(1) during the pendency of the application, access to the cultures will be made available to one determined by the Commissioner to be entitled thereto;
(2) any restrictions on availability of the deposits to the public will be irrevocably removed upon the granting of a patent;
(3) the deposits will be maintained for a term of at least of 30 years from the

date of deposit and at least 5 years after the last request for the material; (4) a viability statement in accordance with the provisions of 37 CFR 1.807; and (5) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

Assurance may be provided in the form of an affidavit, declaration or averment under oath or by a statement of the attorney of record over her or his signature and registration number.

The specification must also state the date of deposit, the number granted by the depository and the name and address of the depository. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

It has not been determined if the microbes of claims 10, 12, 14, 23, 26 are already commercially available or if they are applicants' own constructs. If they are commercially available, a statement to this effect would be sufficient.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13, 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 4,734,367 [A].

The claims are directed to a method for making optically active 3-hydroxy-2-substituted-propionic acid esters comprising: subjecting 2-formylacetic acid ester to a reduction catalyzed by an enzyme source.

US 4,734,367 demonstrates a stereoselective enzymatic reduction of 2-formylacetic acid ester to 3-hydroxy-2-substituted propionic acid. Microbes

used are preferably aerobic or facultative aerobic yeasts, fungi or bacteria (col. 1, l. 68), preferred microbes belong to the genera *Candida* and *Rhodotorula*.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,734,367 [A].

The claims are directed to a method for making optically active 3-hydroxy-2-substituted-propionic acid esters comprising: subjecting 2-formylacetic acid ester to a reduction catalyzed by an enzyme source.

The references are relied upon as explained below.

US 4,734,367 demonstrates a stereoselective enzymatic reduction of 2-formylacetic acid ester to 3-hydroxy-2-substituted propionic acid. Microbes used are preferably aerobic or facultative aerobic yeasts, fungi or bacteria (col. 1, l. 68). This disclosure encompasses the use of any yeast, fungi or bacteria in a method of stereoselective reduction of the substrate. In the absence of evidence of criticality regarding applicants' selected yeast, fungi or bacteria, the use of any yeast, fungi or bacteria in the method is obvious.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions of microbes recited in the claims in order

to obtain the resulting compound as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

REQUEST FOR INFORMATION

Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure.

The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

In response to this requirement, please provide answers to each of the following interrogatories eliciting factual information:

The examiner has failed to find in the prior art, the chemical reaction in claim 17 where an acetic ester derivative of formula (1) is reacted with a base and a formic ester thereby converting the acetic ester derivative into a 2-formylacetic ester derivative of formula (2). This is the first step of the claim.

Please supply the reference which teaches this reaction or make a statement on the record that the inventors believe themselves to be the first inventors of this particular chemical reaction.

Conclusion

This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). It is applicants' burden to indicate how amendments are supported by the ORIGINAL disclosure. Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

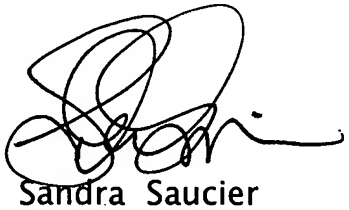
Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to the office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the

examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sandra Saucier
Primary Examiner
Art Unit 1651